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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/581,757 | 03/02/2007 | Shinji Yamasaki | SHIM-018 | 7036 |
| 24353 7590 05/01/2008 BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303 | | | | |
| EXAMINER | | | | |
| CARLSON, KAREN C | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1656 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/581,757

Applicant(s)

YAMASAKI ET AL.

Examiner

Karen Cochrane Carlson, Ph.D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

Art Unit: 1656

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, drawn to poly nucleotide encoding and the polypeptide of SEQ ID NO: 2.

Group 2, claim(s) 1-5, drawn to poly nucleotide encoding and the polypeptide of SEQ ID NO: 3.

Group 3, claim(s) 1-5, drawn to poly nucleotide encoding and the polypeptide of SEQ ID NO: 4.

Group 4 claim(s) 1-5, drawn to poly nucleotide encoding and the polypeptide of SEQ ID NO: 52.

Group 5, claim(s) 1-5, drawn to poly nucleotide encoding and the polypeptide of SEQ ID NO: 53.

Group 6, claim(s) 1-5, drawn to poly nucleotide encoding and the polypeptide of SEQ ID NO: 54.

Group 7, claim(s) 6, drawn to antibody against polypeptide of SEQ ID NO: 2.

Group 8, claim(s) 6, drawn to antibody against polypeptide of SEQ ID NO: 3.

Group 9, claim(s) 6, drawn to antibody against polypeptide of SEQ ID NO: 4.

Group 10, claim(s) 6, drawn to antibody against polypeptide of SEQ ID NO: 52.

Group 11, claim(s) 6, drawn to antibody against polypeptide of SEQ ID NO: 53.

Group 12, claim(s) 6, drawn to antibody against polypeptide of SEQ ID NO: 54.

Group 13, claim(s) 7-30, drawn to methods of detecting *C. coli* via primers, amplification, and kits comprising primers.

Group 14, claim(s) 7-30, drawn to methods of detecting *C. jejuni* via primers, amplification, and kits comprising primers.

Group 15, claim(s) 7-30, drawn to methods of detecting *C. fetus* via primers, amplification, and kits comprising primers.

The inventions listed as Groups 1-15 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The polypeptides as drawn to Inventions 1-7 differ in structure and in function. For example, while SEQ ID NO: 2 and 52 are referred to as *cdtA*, SEQ ID NO: 3 and 53 are referred to as *cdtB*, and SEQ ID NO: 4 and 54 are referred to as *cdtC*, their structures are wholly dissimilar.

NO: 2: Met Gln Lys Ile Lys Leu Ser Met Phe.....

NO: 52: Met Thr Lys Ile Ile Phe Lys His Ile Lys.....

NO: 3: Met Lys Lys Ile Val Phe Leu Ile Leu Ser....

NO: 53: Met Val Phe Ala Pro Ala Ala Ala Ser Trp....

NO: 4: Met Lys Lys Phe Phe Ile Leu Phe Phe Ala....

NO: 54: Met Lys Ala Leu Ala Ile Ile Phe Leu Phe....

Therefore, the subject matter of the polypeptides lack unity because they differ in structure and in function.

The polynucleotides of Groups 1-6 and the antibodies of Groups 7-12 are not used in the methods of Groups 13-15 (which methods use primers) and therefore Groups 1-12 do not share a special technical feature with Groups 13-15.

The primers to detect *C. coli*, *C. jejuni*, or *C. fetus* also differ in sequence and therefore Groups 13-15 do not share a special technical feature.

Art Unit: 1656

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson, Ph.D./
Primary Examiner, Art Unit 1656